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10/501,187	01/13/2006	Rhonda Hansen	20366-124US1	3472

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Julia R. Rosenthal
Chiron Corporation
Intellectual Property
P. O. Box 8097
Emeryville, CA 94662-2916

EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,187	HANSEN, RHONDA	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-29 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *August 28, 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignments #1, #2, and #3*.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment after Final filed January 13, 2010.

Claims 21 and 36 have been amended.

Claims 21-29 and 31-39 are pending in the instant application.

Claims 21-29 and 31-39 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawal of Finality

In view of Applicant's Amendment after Final filed January 13, 2010, and after careful reconsideration of the claims, a new ground(s) of rejection is made of record as detailed below. Therefore, the finality of the Office Action mailed October 16, 2009 is withdrawn.

Information Disclosure Statement

In the previous Office Action mailed October 16, 2009, Applicant's information disclosure statement filed August 28, 2009 was acknowledged. However, it was noted that a copy of Citation No.54, WO 93/19191-A1 could not be located in the file and therefore, the reference was not considered.

After careful reconsideration of Applicant's information disclosure statement filed August 28, 2009, it was noted that Citation No.54, WO 93/19191-A1 is contained within the file, however, only the Abstract is translated in the English language. Therefore, the

Examiner has considered Applicant's information disclosure statement filed August 28, 2009. However, only the Abstract of Citation No.54, WO 93/19191-A1 has been considered by the Examiner. Additionally, regarding Citation No.37, EP-0345242-A2, this reference has not been provided. Therefore, Citation No.37, EP-0345242-A2 has not been considered as the reference has been lined through.

Claim Objections

In the previous Office Action mailed October 16, 2009, claim 21 was objected to because it was grammatically incorrect. **This objection is withdrawn** in view of Applicant's Amendment after Final filed January 13, 2010. It is noted that Applicant's Amendment after Final filed January 13, 2010 has remedied the grammatical error.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed October 16, 2009, claims 21-29 and 31-34 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994). **This rejection is withdrawn** in view of Applicant's Amendment after Final filed January 13, 2010. Specifically, the Examiner is withdrawing this rejection in view of Applicant's arguments that "DKFZp5661133" is explicitly defined in the specification. The Examiner acknowledges that "DKFZp566I133" has been explicitly defined in Applicant's specification at pages 11 and 12, for example. Therefore, given the explicit definition of "DKFZp566I133" as detailed in Applicant's specification, the interpretation of "DKFZp566I133" to encompass the human vesicle membrane protein-like protein of

'994 is not consistent with Applicant's definition. Therefore, this rejection is withdrawn.

In the previous Office Action mailed October 16, 2009, claims 35 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994) as applied to claims 21-29 and 31-34 and 37 above, and further in view of U.S. Patent No. 6,844,325 ('325). **This rejection is withdrawn** in view of Applicant's Amendment after Final filed January 13, 2010. As noted above, the Examiner is withdrawing this rejection in view of Applicant's arguments that "DKFZp566I133" is explicitly defined in the specification. The Examiner acknowledges that "DKFZp566I133" has been explicitly defined in Applicant's specification at pages 11 and 12, for example. Therefore, given the explicit definition of "DKFZp566I133" as detailed in Applicant's specification, the interpretation of "DKFZp566I133" to encompass the human vesicle membrane protein-like protein of '994 is not consistent with Applicant's definition. Therefore, this rejection is withdrawn.

After careful reconsideration of the claims, a new ground(s) of rejection is made of record as detailed below:

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application 60345637, filed 01/08/2002, and PCT/US03/00657, filed 01/08/2003 fails to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. It should be noted that the Provisional Application and PCT/US03/00657 do not have support for instant claims as now drawn. Specifically, support cannot be found for the term "DKFZp56611233". While "DKFZp566I1233" appears throughout these two parent applications, the term "DKFZp56611233" is not supported. In this regard, the instant claims have been afforded priority to filing date of the instant application which is 1/13/2006.

If Applicants believe that the claims are entitled to an earlier priority date, the Examiner urges Applicant to specifically point out, with particularity, where support can be found for the term, "DKFZp56611233" in Provisional Application 60345637 and PCT/US03/00657.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-29 and 31-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The issue is that the claims recite the term, "DKFZp56611233". The term, "DKFZp56611233" does not appear to be recited in Applicant's specification or claims as originally filed. While "DKFZp566I1233" appears throughout Applicant's specification and claims as originally filed, the term "DKFZp56611233" is not supported.

Should Applicants disagree, Applicant is encouraged to point out, with particularity, by page and line number where support for the term "DKFZp56611233" exists.

Applicants are required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-26 and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. PreGrant Publication 20030124128.

Claims 21-26 and 31 are drawn to a method for identifying a cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate agent with a cell that expresses DKFZp56611233; and detecting a difference between the biological activity of DKFZp56611233 in the presence and absence of the candidate agent, wherein a difference between the level of biological activity of DKFZp56611233 in the presence and absence of the candidate agent indicates that the candidate agent is a cancer therapeutic, wherein said cancerous cell and said normal cell are breast cells; wherein said detecting is by assessing expression of said gene product; where expression is assessed by detecting a polypeptide gene product; and wherein said candidate agent is an antisense polynucleotide. Claims 32-35 are drawn to a method of screening a candidate agent to identify a cancer therapeutic comprising (a) contacting cells that expresses DKFZp56611233 with a candidate agent; and (b) detecting a difference between the level of expression of DKFZp56611233 in the presence and absence of the candidate agent, wherein a difference between the level of DKFZp56611233 expression in the presence and in the absence of the candidate agent indicates that the candidate agent is a cancer therapeutic, wherein a difference in expression levels of DKFZp56611233 is detected using a polymerase chain reaction, hybridization, or Western blot; and wherein the cancer is breast cancer.

It is noted that the instant specification, at the last paragraph bridging pages 11 and 12 states:

> "[A]lternatively, "DKFZp566I133" or "DKFZ" refers to an amino acid sequence defined by NCBI accession number NP_112200, AAH09758, NM_138839, and NM_030938, polynucleotides encoding the amino acid sequences set forth in these accession numbers (SEQ ID NO:512 and SEQ ID NO:513), respectively"

U.S. PreGrant Publication 20030124128 discloses novel genes associated with breast cancer. U.S. PreGrant Publication 20030124128 teaches methods of identifying modulators and a method of screening for modulators (i.e. test compounds or agents) that bind to SEQ ID NO:144. It is noted that SEQ ID NO:144 of U.S. PreGrant Publication 20030124128 encodes an amino acid sequence that is 100% identical to SEQ ID NO:512 as represented in Applicant's invention. See attached sequence alignment #3. Further, U.S. PreGrant Publication 20030124128 has identified SEQ ID NO:114 as DKFZp566I133 (see Drawings at page 2). U.S. PreGrant Publication 20030124128 teaches that the breast cancer samples (normal and cancerous) are obtained from a patient and compounds known to be effective for inhibiting SEQ ID NO:114 are tested to identify compounds efficacious for inhibiting breast cancer in the patient. U.S. PreGrant Publication 20030124128 teaches that sequences of their invention can be inhibited using an antisense oligonucleotide.

U.S. PreGrant Publication 20030124128 teaches that a gene product or a polypeptide is assessed. U.S. PreGrant Publication 20030124128 also teaches that the level of expression is detected by polymerase chain reaction or Western blot.

It is noted that U.S. PreGrant Publication 20030124128 teach methods of

screening for agents that modulate "DKFZp566I133" or SEQ ID NO:512 of Applicant's invention. However, U.S. PreGrant Publication 20030124128 is silent regarding methods of screening agents to identify a cancer therapeutic. However, Applicant is reminded that the burden of establishing whether the prior art has the further function of identifying a cancer therapeutic under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that the methods of screening for agents that modulate "DKFZp566I133" or SEQ ID NO:512 of Applicant's invention disclosed by U.S. PreGrant Publication 20030124128 would or

would not have the additional functional limitation of identifying a cancer therapeutic agent as claimed in Applicant's invention.

Therefore, U.S. PreGrant Publication 20030124128 anticipates claims 21-26 and 31-35, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-29, 31-34, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/60860 A2 in view of WO 01/12662 A2.

Claim 21 is drawn to a method for identifying a cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate agent with a

cell that expresses DKFZp56611233; and detecting a difference between the biological activity of DKFZp56611233 in the presence and absence of the candidate agent, wherein a difference between the level of biological activity of DKFZp56611233 in the presence and absence of the candidate agent indicates that the candidate agent is a cancer therapeutic. Claims 22-29 31, 34, and 37-39 are dependent on claim 21 and include all the limitations of claim 21 with the further limitations wherein said cancerous cell and said normal cell are breast cells; wherein said detecting is by assessing expression of said gene product; where expression is assessed by detecting a polypeptide gene product; wherein said candidate agent is an antisense polynucleotide; wherein said biological activity is modulation of a cancerous phenotype; wherein said cancerous phenotype is abnormal cellular proliferation; wherein said phenotype is loss of contact inhibition; wherein the agent is a DKFZ antisense polynucleotide which inhibits DKFZ gene expression by at least 90%; wherein the cancer is breast cancer; wherein the biological activity is cell growth, proliferation, or invasiveness; wherein the cancerous cell and normal cell are other than breast cancer cells; and wherein the cancer is other than breast cancer. Claim 32 is drawn to a method of screening a candidate agent to identify a cancer therapeutic comprising (a) contacting cells that expresses DKFZp56611233 with a candidate agent; and (b) detecting a difference between the level of expression of DKFZp56611233 in the presence and absence of the candidate agent, wherein a difference between the level of DKFZp56611233 expression in the presence and in the absence of the candidate agent indicates that the candidate agent is a cancer therapeutic. Claims 33 and 34 are dependent on claim 32 and include

all the limitations of claim 32 with the further limitations wherein a difference in expression levels of DKFZp56611233 is detected using a polymerase chain reaction, hybridization, or Western blot; and wherein the cancer is breast cancer.

Applicant is reminded that the instant specification, at the last paragraph bridging pages 11 and 12 states:

> "[A]lternatively, "DKFZp566I133" or "DKFZ" refers to an amino acid sequence defined by NCBI accession number NP_112200, AAH09758, NM_138839, and NM_030938, polynucleotides encoding the amino acid sequences set forth in these accession numbers (SEQ ID NO:512 and SEQ ID NO:513), respectively"

Determining the scope and contents of the prior art

WO 01/60860 teaches novel genes associated with prostate cancer. WO 01/60860 teaches methods of identifying modulators and a method of screening for modulators (i.e. test compounds or agents) that bind to SEQ ID NO:29252. It is noted that SEQ ID NO:29252 of WO 01/60860 comprises 100% of SEQ ID NO:513 as represented in Applicant's invention. See attached sequence alignment #1. WO 01/60860 teaches that the prostate cancer samples (normal and cancerous) are obtained from a patient and compounds known to be effective for inhibiting SEQ ID NO:29252 are tested to identify compounds efficacious for inhibiting prostate cancer in the patient. WO 01/60860 teaches that sequences of their invention can be inhibited using an antisense oligonucleotide.

WO 01/60860 teaches that a gene product or the polypeptide is assessed. WO 01/60860 also teaches that the level of expression is detected by polymerase chain reaction or Western blot.

Ascertaining the differences between the prior art and the claims at issue

WO 01/60860 does not necessarily teach that the cells are breast cells, cancerous or otherwise.

WO 01/12662 teaches methods for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein the polynucleotide comprises SEQ ID NO:54. It is noted that SEQ ID NO:54 of WO 01/12662 comprises 100% of SEQ ID NO:513 as represented in Applicant's invention. See attached sequence alignment #2. WO 01/12662 teaches that the compound is an antisense compound and the cells are cancers of the breast.

It is noted that WO 01/60860 A2 and WO 01/12662 A2 both teach methods of screening for agents that modulate "DKFZp566I133" or SEQ ID NO:513 of Applicant's invention. However, both are silent as to methods of screening agents to identify a cancer therapeutic. Applicant is reminded that the burden of establishing whether the prior art has the further function of identifying a cancer therapeutic under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by

evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that the methods of screening for agents that modulate "DKFZp566I133" or SEQ ID NO:513 of Applicant's invention disclosed by WO 01/60860 A2 and WO 01/12662 A2 would or would not have the additional functional limitation of identifying a cancer therapeutic agent as claimed in Applicant's invention.

Resolving the level of ordinary skill in the pertinent art

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to devise a method for identifying an anti-cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate anti-cancer agent with a cell that expresses SEQ ID NO:513 of Applicant's invention using the teachings and motivation of WO 01/60860 A2 and WO 01/12662 A2. It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was

made to devise a method of screening a candidate agent for anti-cancer activity comprising (a) contacting cells that expresses SEQ ID NO:513 of Applicant's invention with a candidate agent; and (b) detecting a difference between the level of expression of SEQ ID NO:513 of Applicant's invention in the presence and absence of the candidate agent, wherein a difference between the level of SEQ ID NO:513 of Applicant's invention expression in the presence and in the absence of the candidate agent indicates that the candidate agent has anti-cancer activity using the teachings and motivation of WO 01/60860 A2 and WO 01/12662 A2.

One of ordinary skill in the art would have been motivated to devise a method for identifying an anti-cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate anti-cancer agent with a cell that expresses SEQ ID NO:513 of Applicant's invention since WO 01/60860 A2 teaches that a gene encoding SEQ ID NO:513 of Applicant's invention is a potential marker of prostate cancer. One of ordinary skill in the art would have been motivated to devise a method of screening a candidate agent for anti-cancer activity comprising (a) contacting cells that expresses SEQ ID NO:513 of Applicant's invention with a candidate agent; and (b) detecting a difference between the level of expression of SEQ ID NO:513 of Applicant's invention in the presence and absence of the candidate agent, wherein a difference between the level of SEQ ID NO:513 of Applicant's invention expression in the presence and in the absence of the candidate agent indicates that the candidate agent has anti-cancer

activity since WO 01/60860 A2 taught that a gene encoding SEQ ID NO:513 of Applicant's invention is a potential marker of prostate cancer.

One of ordinary skill in the art would have had a reasonable expectation of devising a method for identifying an anti-cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate anti-cancer agent with a cell that expresses SEQ ID NO:513 of Applicant's invention since both WO 01/60860 A2 and WO 01/12662 A2 taught that such a method was routine and well-known in the art at the time of filing. One of ordinary skill in the art would have had a reasonable expectation of devising a method of screening a candidate agent for anti-cancer activity comprising (a) contacting cells that expresses SEQ ID NO:513 of Applicant's invention with a candidate agent; and (b) detecting a difference between the level of expression of SEQ ID NO:513 of Applicant's invention in the presence and absence of the candidate agent, wherein a difference between the level of SEQ ID NO:513 of Applicant's invention expression in the presence and in the absence of the candidate agent indicates that the candidate agent has anti-cancer activity since both WO 01/60860 A2 and WO 01/12662 A2 taught that such a method was routine and well-known in the art at the time of filing.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

******

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/60860 A2 in view of WO 01/12662 A2 as applied to claims 21-29, 31-34, and 37-39, and further in view of U.S. Patent No. 6,844,325 ('325) (of record).

Claim 32 is as described above. Claims 35 and 36 are dependent on claim 32 and include all the limitations of claim 32 with the further limitations wherein the DKFZ antisense polynucleotide comprises a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513; and wherein the DKFZ antisense polynucleotide comprises a nucleotide sequence of SEQ ID NO:508.

Determining the scope and contents of the prior art

WO 01/60860 A2 and WO 01/12662 A2 are relied upon as described above.

Ascertaining the differences between the prior art and the claims at issue

Neither WO 01/60860 A2 or WO 01/12662 A2 necessarily teach wherein the DKFZ antisense polynucleotide comprises a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 or wherein the DKFZ antisense polynucleotide comprises a nucleotide sequence of SEQ ID NO:508.

‘325 teach a cDNA sequence of clone 21053 (see SEQ ID NO:458). '325 also teach that cDNAs of their invention are in the antisense orientation. It is noted that SEQ ID NO:458 taught by ‘325 comprises the entire sequence of SEQ ID NO:508 of Applicant’s invention (see sequence alignment provided in Office Action mailed January 16, 2009). It is also noted that SEQ ID NO:458 disclosed by ‘325 comprises a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513.

It is noted that ‘325 is silent regarding whether the cDNA sequence represented

by SEQ ID NO:458 could be used as an antisense to inhibit DKFZ expression. However, the burden of establishing whether the prior art antisense cDNA could be used to inhibit gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that prior art antisense cDNA disclosed by '325 would or would not inhibit DKFZ gene expression as instantly claimed.

Resolving the level of ordinary skill in the pertinent art

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to have the DKFZ antisense polynucleotide comprises a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 or have the DKFZ antisense polynucleotide comprise a nucleotide sequence of SEQ ID NO:508 using the teachings and motivation of '325.

One of ordinary skill in the art would have been motivated to have the DKFZ antisense polynucleotide comprise a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 since both WO 01/60860 A2 and WO 01/12662 A2 taught antisense targeting to a gene encoding SEQ ID NO:513 of Applicant's invention. One of ordinary skill in the art would have been motivated to have the DKFZ antisense polynucleotide comprise a nucleotide sequence of SEQ ID NO:508 since '435 taught that such a sequence could be used as an antisense.

One of ordinary skill in the art would have had a reasonable expectation of having the DKFZ antisense polynucleotide comprise a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 since both WO 01/60860 A2 and WO 01/12662 A2 taught antisense targeting to a gene encoding SEQ ID NO:513 of Applicant's invention. One of ordinary skill in the art would have had a reasonable expectation of having the DKFZ antisense polynucleotide comprise a nucleotide sequence of SEQ ID NO:508 since '435 taught that, at the time of invention, such a sequence could be used as an antisense oligonucleotide.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

Conclusion/Allowable Subject Matter

No claims are allowable. However, the prior art does not teach or fairly suggest a method for identifying a cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, said method comprising contacting a candidate agent with a cell that expresses DKFZp566I1233; and detecting a difference between the biological activity of DKFZp566I1233 in the presence and absence of the candidate agent, wherein a difference between the level of biological activity of DKFZp566I1233 in the presence and absence of the candidate agent indicates that the candidate agent is a cancer therapeutic, wherein the agent is an antisense polynucleotide consisting of SEQ ID NO:508. Additionally, the prior art does not teach or fairly suggest a method of screening a candidate agent to identify a cancer therapeutic comprising (a) contacting cells that expresses DKFZp566I1233 with a candidate agent; and (b) detecting a difference between the level of expression of DKFZp566I1233 in the presence and absence of the candidate agent, wherein a difference between the level of DKFZp566I1233 expression in the presence and in the absence of the candidate agent indicates that the candidate agent is a cancer therapeutic, wherein the agent is an antisense polynucleotide consisting of SEQ ID NO:508.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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February 3, 2010
/Terra Cotta Gibbs/

/Sean R McGarry/
Primary Examiner, Art Unit 1635